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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/824,304 | 04/14/2004 | Lucio Giambattista | P-5023D1 | 5970 |
| 7590 | 08/02/2006 | | EXAMINER | |
| Becton, Dickinson and Company 1 Becton Drive Franklin Lakes, NJ 07417 | | | GILBERT, ANDREW M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3767 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/824,304 | Applicant(s) GIAMBATTISTA ET AL. | |
| | Examiner Andrew M. Gilbert | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-26,31-40,45-47 and 50-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-26,31-40,45-47 and 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 6/5/2006.
2. In the reply, the Applicant cancelled claims 27-30, 41-44, 48-49, and 56-57. Claims 1-23 were previously cancelled. Thus, claims 24-26, 31-40, 45-47 and 50-55 remain pending.
3. Additionally, the Applicant amended the specification and replacement drawing sheet Figure 7 to provide proper antecedent basis and support for the claimed subject matter. No new matter was added. Thus, the objection to the drawings and specification has been withdrawn.
4. Additionally, the objection to claims 25-35, 37-44, 46-49, 51-52, 54-57 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn due to cancellation of claims and amendments to the specification providing a written description of an indicating area and visual indication.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 24, 31, 36, 45, 50, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Berthier (5429612). In reference to claim 24, Berthier discloses a safety injection needle assembly (1) having an injection needle (6) with an injection end and a

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cartridge end (Fig 1), the needle being mounted in a hub (2; Fig 1-3; col 3, lns 23-27), a slideable safety shield (10) being biased to longitudinally slide toward and cover the injection end of the needle in the normal unused state (Fig 1), a lock (26, 29) that is activated by sliding the shield from its biased position to a position exposing the injection end of the needle during an injection (col 4, ln 33-col 5, ln 17) and a visual indicator (26 – outer side of resilient tongue 26 can be viewed as it slides along groove 22 and is pushed outward by 28 and then retracts downward and locks in place in 29) that indicates that the safety shield is locked in the normally biased position (Fig 2-3).

7. In reference to claim 31, it is noted that the applicant has invoked 35 U.S.C. 112(6th) paragraph in claims 31, pg 5, ln 6 by fulfilling the 3-pronged test by reciting “means for” language, reciting function, and by not including or reciting sufficient structure of the means referred to in the specification. Berthier discloses the invention substantially as claimed and additionally discloses a locking means for irreversibly locking the safety shield in the second position covering the injection end of the needle being a lock (26, 29) that is activated by sliding the shield from its biased position to a position exposing the injection end of the needle during an injection (col 4, ln 33-col 5, ln 17).

8. In reference to claim 36, Berthier discloses the invention substantially as claimed except for additionally disclosing that the needle hub has a proximal end having a fastening mechanism (2) for mounting the needle hub onto a syringe having a cartridge (4), an injection end of the needle that is capable of subcutaneous injection (col 2, lns 48-56), and a cartridge end that extends into the interior of the cartridge (Fig 1).

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9. In reference to claims 45 and 50, Berthier discloses the invention substantially as claimed and additionally discloses a vial end (6; 2; 5; Fig 1; col 3, lns 10-22) and a lock and safety shield that are constructed and arranged to provide a visual indication that the safety shield is locked in the normally biased position (col 4, ln 33-col 5, ln 17 – see above discussion in regards to claim 24).

10. In reference to claim 53, Berthier discloses the invention substantially as claimed and additionally discloses a needle hub having a closed end (2) and an open end (opposite end of 2 seen in Fig 1), the open end being provided with a thread (seen on 3; col 3, lns 10-15) to mount the needle hub to an injector having a vial (4) covered by the needle hub (2).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 25-26, 32-35, 37-40, 46-47, 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthier in view of Lewandowski (5674203).

13. In reference to claims 25-26, 32-35, 37-40, 46-47, 51-55, Berthier discloses the invention substantially as claimed except for the safety shield having a transparent area or an opening through which the indicating areas are visible, the indicating areas and additionally indicating areas providing difference visual indications, and the visual indication showing a colored surface or textured surface after the shield is irreversibly

locked. Lewandowski teaches that it is known to have the lock or hub having an indicating area and at least one additional indicating area (Figs 1-13; col 4, ln 46-col 7, ln 13), the safety shield having a transparent area (40; col 5, lns 10-15) or an opening (31) through which the indicating areas are visible (Figs 1-13), the indicating areas and additionally indicating areas providing difference visual indications (Figs 1-13), and the visual indication showing a colored surface (Figs 1-13; col 4, ln 46-col 7, ln 13) or textured surface (Figs 1-13; col 4, ln 46-col 7, ln 13), as any printing or coating will result in a textured surface, after the shield is irreversibly locked for the purpose of providing a visual indication that the needle guard is in the extended and locked position without the need for further testing on the part of the user (col 4, lns 58-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the needle shield as taught by Berthier with the needle shield as taught by Lewandowski for the purpose of providing a visual indication that the needle guard is in the extended and locked position without the need for further testing on the part of the user (col 4, lns 58-61).

Response to Arguments

14. Applicant's arguments filed 6/5/2006 have been fully considered but they are not persuasive.

15. The Applicant argues that Berthier does not disclose and show a visual difference between the pre-use and post-use positions of the needle protector.

16. As discussed in the Interview on 5/11/2006, claims 24, 31, 36, 45, 50, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Berthier (5429612). Berthier

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does disclose and show a visual difference between the pre-use and post-use positions of the needle protector. The resilient tongue (26; Fig 2, 3) has a outer surface that is visible to the user (as shown in Figure 2, there is a gap between the tongue (26) and the protector (8) wherein it is clear that the tongue is visibly separate from the protector). The resilient tongue moves along groove (24) and as it moves along (28) the resilient tongue is move outwardly, which can be visually seen by the user, and then as the resilient tongue (26) engages prawl (29) the tongue will move inwardly into the space created by recess (29) and will be subsequently locked in place. The visual difference between the pre-use position (resilient tongue (26) is in groove (23)) and post-use position (resilient tongue (26) passes through groove (24) up (28) and into recess (29)) where the shield is permanently locked in place in recess (29) is apparent by visually observing the outer surface of resilient tongue (26).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

